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44

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
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| 09/031,629 | 02/27/98 | FAUSTMAN | D 11275/73537 |

HM12/0201

EXAMINER

NOLAN, P

ART UNIT

PAPER NUMBER

1644

4

DATE MAILED: 02/01/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

| | | | |
|-----------------|------------|----------------|-----------------|
| Application No. | 09/031,629 | Applicant(s) | Faustman et al. |
| Examiner | Nolan | Group Art Unit | 1644 |

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Response

A SHORTENED STATUTORY PERIOD FOR RESPONSE IS SET TO EXPIRE 30 days MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a response be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for response specified above is less than thirty (30) days, a response within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for response is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication .
- Failure to respond within the set or extended period for response will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- Responsive to communication(s) filed on _____.
- This action is **FINAL**.
- Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 1 1; 453 O.G. 213.

Disposition of Claims

Claim(s) 1-64 is/are pending in the application.

Of the above claim(s) _____ is/are withdrawn from consideration.

Claim(s) _____ is/are allowed.

Claim(s) _____ is/are rejected.

Claim(s) _____ is/are objected to.

Claim(s) 1-64 are subject to restriction or election requirement.

Application Papers

- See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- The proposed drawing correction, filed on _____ is approved disapproved.
- The drawing(s) filed on _____ is/are objected to by the Examiner.
- The specification is objected to by the Examiner.
- The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
 - All
 - Some*
 - None of the CERTIFIED copies of the priority documents have been
 - received.
 - received in Application No. (Series Code/Serial Number) _____.
 - received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

Attachment(s)

- Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
- Notice of References Cited, PTO-892
- Notice of Draftsperson's Patent Drawing Review, PTO-948
- Interview Summary, PTO-413
- Notice of Informal Patent Application, PTO-152
- Other _____

Office Action Summary

Part III DETAILED ACTION

1. **Please Note:** In an effort to enhance communication with our customers and reduce processing time, Group 1640 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your responses. The Fax number is 703-305-3704. A Fax cover sheet is attached to this Office Action for your convenience. We encourage your participation in this Pilot program. If you have any questions or suggestions please contact Paula Hutzell, Supervisory Patent Examiner at 703-308-4310. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.

2. Claims 1-64 are pending.

Restriction/Election

3. Restriction to one of the following inventions is required under 35 U.S.C. 121:

Group I. Claims 1-7, drawn to a method of detecting an autoimmune disease by detecting proteosome activity, classified in class 435, subclass 7.4.

Group II. Claims 8-13, drawn to a method of detecting an autoimmune disease by detecting protein ubiquination, classified in class 435 subclass 7.8.

Group III. Claims 14-19, drawn to a method of detecting an autoimmune disease by detecting protein phosphorylation, classified in class 435 subclass 7.1.

Group IV. Claims 20-26, drawn to a method of detecting an autoimmune disease by detecting NFKB activity, classified in class 435 subclass 7.8.

Group V. Claims 27-33, drawn to a method of detecting autoimmune diseases by detecting cell survival or growth, classified in class 435 subclass 29.

Group VI. Claims 34-40, drawn to a method of treating an autoimmune disease by restoring ubiquinating enzyme function, classified in class 424, subclass 94.1 and class 514, subclass 44.

Group VII. Claims 41-48, drawn to a method of treating an autoimmune disease by restoring NFKB activity, classified in class 424, subclasses 85.1, 94.1 and 184.1 and class 514, subclass 44.

Group VIII. Claims 49-56, drawn to a method of treating an autoimmune disease by restoring lymphocyte maturation, classified

in class 424, subclasses 85.1, 94.1 and 184.1 and class 514, subclass 44.

Group IX. Claims 57-64, drawn to a method of treating an autoimmune disease by restoring lymphocyte maturation, classified in class 424, subclasses 85.1, 94.1 and 184.1 and class 514, subclass 44.

4. The inventions are distinct, each from the other because of the following reasons:

Groups I-V are unique methods. They differ with respect to ingredients. Detecting autoimmune diseases by detecting proteosome activity or protein ubiquination or protein phosphorylation or NFkB activity or cell survival or growth are all patentably distinct because each method is detecting a physically and chemically distinct product and therefore represent patentably distinct subject matter.

Groups VI-IX are unique methods. They differ with respect to ingredients. Treating autoimmune diseases by restoring protein ubiquination or NFkB activity or lymphocyte maturation or the cell cycle are all patentably distinct because each method has a unique physiologically distinct endpoint and are therefore represent patentably distinct subject matter.

Groups I-V and VI-IX are unrelated methods and are therefore patentably distinct. Methods of detection are patentable distinct from methods of treatment, as evidenced by their separate classifications.

5. Because a search of these nine distinct inventions would not be co-extensive with a search of the others, an examination and search of two or more inventions in a single application would constitute a serious undue burden on the examiner.

6. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

8. Applicant is advised that the response to this requirement to

be complete must include an election of the invention to be examined even though the requirement be traversed.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patrick Nolan whose telephone number is (703) 305-1987. The examiner can normally be reached on Monday through Thursday from 8:00 am to 5:30 pm.

10. If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Christina Chan, can be reached at (703) 305-3973. The FAX number for our group, 1644, is (703) 305-3014. Any inquiry of a general nature relating to the status of this application or proceeding should be directed to the Group receptionist, whose telephone number is (703) 308-0196.

Patrick Nolan, Ph.D.
January 28, 1999

Patrick J. Nolan
Patrick Nolan, Ph.D.
Patent Examiner
Group 1640



RESTRICTION ELECTION FACSIMILE TRANSMISSION

DATE:

FROM/ATTORNEY:

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COMMENTS: _____

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